

Remarks

Reconsideration and allowance of this application, as amended, are respectfully requested.

Claims 1, 4, 10, 18, and 20 have been amended. Claim 3 has been canceled without prejudice or disclaimer. New claim 21 has been added. Claims 1, 2, and 4-21 are now pending in the application, with claims 12-15 withdrawn from consideration as directed to a non-elected invention. Claims 1, 18, and 21 are independent. The rejections are respectfully submitted to be obviated in view of the amendments and remarks presented herein. No new matter has been introduced through the foregoing amendments.

Claim 1 has been amended to incorporate a feature of the invention previously recited in now-canceled claim 3. Instant claim 1 defines a bicompartment bag adapted to prepare a liquid solution that includes in pertinent part "an assembly of two strong flexible outer sheets and a flexible inner sheet that divides an interior of the bag into a first chamber *that is at least partially filled with a powdered solute* and a second chamber." Claim 18 has been amended in a parallel manner. Applicant submits that instant claims 1 and 18 are allowable for the reasons outlined below.

Applicant also acknowledges with gratitude the indication of allowable subject matter in claims 5-9, 11, 16, 17, 19, and 20. Accordingly, new independent claim 21 has been added. Claim 21

combines the features of previously presented claims 1 and 5.
Entry of the amendments is respectfully requested.

35 U.S.C. § 103(a) - Rochat and Macabasco

Claims 1 and 2 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over US 5,269,924 to Rochat in view of US 5,573,527 to Macabasco et al. (hereinafter "Macabasco").

The rejection of claims 1 and 2 under § 103(a) based on Rochat and Macabasco is respectfully deemed to be obviated. For at least the following reasons, the combined disclosures of Rochat and Macabasco would not have rendered obvious Applicant's instantly claimed invention.

By way of review, Applicant's claim 1 is directed to a bicompartment bag that is adapted to prepare a liquid solution from a powdered solute. As disclosed at specification page 2, lines 22-26, Applicant's invention

provides a new, extremely simple constructive procedure, to make it suitable to optimally attain its objects, including providing a means to divide the container into two separate chambers, in one of which the powdered product to be converted into a concentrate used in haemodialysis is to be stored.

One feature of Applicant's bicompartment bag is that it facilitates mixing of the powdered solute and a solvent with a construction that is simpler than that of prior art devices. Another feature of Applicant's bag is that it has a construction

that facilitates testing of the structural integrity of each bag prior to use.

As indicated above, claim 1 has been amended to incorporate a feature of the invention previously recited in now-canceled claim 3. Instant claim 1 defines a bicompartiment bag adapted to prepare a liquid solution that includes in pertinent part "an assembly of two strong flexible outer sheets and a flexible inner sheet that divides an interior of the bag into a first chamber *that is at least partially filled with a powdered solute* and a second chamber."

The combined disclosures of Rochat and Macabasco do not teach all of Applicant's claim features. More specifically, Rochat and Macabasco do not teach the claimed feature of the "first chamber that is at least partially filled with a powdered solute." In fact, the examiner even acknowledges as much, stating that "Rochat and Macabasco et al., however, do not disclose that the first chamber is at least partially filled with a powdered solute" (Office Action page 4, numbered paragraph 5). Therefore, the combined disclosures of Rochat and Macabasco would not have rendered obvious the invention defined by instant claim 1. Claim 2 is allowable because it depends from claim 1, and for other reasons.

35 U.S.C. § 103(a) – Rochat, Macabasco, and Mathieu

Claims 3, 4, and 10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Rochat in view of Macabasco, and further in view of US 5,616,305 to Mathieu. The examiner states in pertinent part that “[t]he use of sodium bicarbonate for dialysis treatment of blood is established in the art, especially when used in conjunction with blood bags” (Office Action page 4, numbered paragraph 5). The examiner also states that “[f]urthermore, in the blood bag system disclosed by Rochat, it is inherent that the layer of sodium bicarbonate would be located in the first chamber 13, before the filtering layer 18 [sic, 12], in order to prevent particles from mixing into the blood” (Office Action page 4, numbered paragraph 5).

As indicated above, the feature of claim 3 is now incorporated in instant claim 1. In support of the patentability of claim 1, Applicant respectfully traverses the rejection of claims 3, 4, and 10 under § 103(a) based on Rochat, Macabasco, and Mathieu. For at least the following reasons, the combined disclosures of Rochat, Macabasco, and Mathieu would not have rendered obvious Applicant's instantly claimed invention.

Rochat is directed to a “Blood Collecting and Filtering Apparatus.” Macabasco is directed to a “Dockable Bag System and Method” and discloses that “[t]he present invention generally relates to the field of *blood bag systems*, and specifically relates

to the field of sterile docking multiple blood bag systems" (column 1, lines 14-16) (emphasis added). Mathieu, however, is directed to a "Flexible Medical Hemodialysis Packaging Unit for the Production of Concentrated Dialysis Solution Including a Device for the Same."

The combined disclosures of Rochat, Macabasco, and Mathieu do not teach all of Applicant's claim features. Furthermore, for at least the following reasons, there would have been no incentive to combine the references. The bag described by Mathieu is used for dry concentrates for the preparation of hemodialysis solution. As described by Mathieu, water is mixed with the powdered salt to produce a liquid concentrate. This concentrate is then further diluted in the device 40 and other concentrates may be added before it is supplied to a dialyser 46 (shown only schematically in Mathieu).

The examiner's statement that "[t]he use of sodium bicarbonate for dialysis treatment of blood is established in the art, especially when used in conjunction with blood bags" is respectfully believed to be a mischaracterization. Blood bags are used in *blood transfusion technology*, not in hemodialysis treatment.

The examiner's assertion that "in the blood bag system disclosed by Rochat, it is inherent that the layer of sodium bicarbonate would be located in the first chamber 13, before the filtering layer 18 [sic, 12], in order to prevent particles from

mixing into the blood" is not only illogical, but incorrect. During dialysis, the blood of a treated patient is circulated through the dialyser wherein the blood is separated from the dialysis fluid by a semipermeable membrane. In the remainder of the hemodialysis device there is *no contact* between the blood and any hemodialysis solution, in particular not in the bag in which the solution is prepared. Furthermore, it would make no sense at all to place any powdered solute into the blood bags of Rochat or Macabasco.

Therefore, the combined disclosures of Rochat, Macabasco, and Mathieu would not have rendered obvious the claimed invention.

35 U.S.C. § 103(a) – Rochat, Macabasco, and Verkaart

Claim 18 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Rochat in view of Macabasco and further in view of US 2002/0030002 of Verkaart et al. ("Verkaart").

The rejection of claim 18 under § 103(a) based on Rochat, Macabasco, and Verkaart is respectfully deemed to be obviated. Claim 18 has been amended to define a bicompartiment bag that includes in pertinent part "a first chamber that is at least partially filled with a powdered solute." The examiner has acknowledged that Rochat and Macabasco "do not disclose that the first chamber is at least partially filled with a powdered solute." The disclosure of Verkaart does not rectify any of the above-

described deficiencies of Rochat and Macabasco. Instant claim 18 is therefore allowable.

In view of the foregoing, this application is now in condition for allowance. If the examiner believes that an interview might expedite prosecution, the examiner is invited to contact the undersigned.

Respectfully submitted,

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Date: October 26, 2007